IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., and NOVOPHARM, LTD., Counterclaim Plaintiffs, v. ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTÉ, and LABORATOIRES FOURNIER S.A., Counterclaim Defendants.	**REDACTED PUBLIC VERSION** C.A. No. 02-1512 (SLR) CONSOLIDATED
IMPAX LABORATORIES, INC., Counterclaim Plaintiff, v. ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTÉ, and LABORATOIRES FOURNIER S.A., Counterclaim Defendants.	C.A. No. 03-120 (SLR) CONSOLIDATED
IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	C.A. No. 05-340 (SLR) CONSOLIDATED
IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	C.A. No. 05-360 (SLR) CONSOLIDATED

OPENING BRIEF IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON THE CLAIMS OF "SHAM LITIGATION" AND *WALKER PROCESS* VIOLATIONS

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Mary B. Graham (#2256)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
mgraham@mnat.com
jparrett@mnat.com

OF COUNSEL:

William F. Cavanaugh, Jr.
Thomas W. Pippert
Chad J. Peterman
Alexis Deise
PATTERSON, BELKNAP, WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
(212) 336-2000

Attorneys for Defendant Abbott Laboratories

RICHARDS, LAYTON & FINGER, P.A.
Frederick L. Cottrell, III (#2555)
Anne Shea Gaza (#4093)
One Rodney Square
P.O. Box 551
Wilmington, DE 19899
(302) 651-7700
cottrell@rlf.com
gaza@rlf.com

OF COUNSEL:

William Baer
James Cooper
Anne P. Davis
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, DC 20004
(202) 942-5000

Timothy C. Bickham
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, N.W.
Washington, DC 20036-1795
(202) 429-5517

Attorneys for Fournier Industrie Et Santé and Laboratoires Fournier, S.A.

Dated: May 5, 2008

Redacted Filing Date: May 12, 2008

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

INTRODUCTION 1

STATEMENT OF UNCONTESTED FACTS 5

A. The Capsule Cases 5

B. The Tablet Cases 6

THE DECISION ON DEFENDANTS' RULE 12(B)(6) MOTION 8

ARGUMENT 8

I. APPLICABLE LEGAL STANDARDS 8

A. The Summary Judgment Standard 8

B. The Noerr-Pennington Doctrine 9

C. The Standards for Claims of "Sham Litigation" 9

D. The Standards for *Walker Process* Claims 11

II. DEFENDANTS' ALLEGATIONS IN THE CAPSULE CASES WERE OBJECTIVELY REASONABLE 12

A. Defendants' Proposed Construction of "Co-Micronized" and "Co-Micronization" Was Reasonable 13

B. Defendants' Construction of "Solid Surfactant" Was Reasonable 17

III. DEFENDANTS' ALLEGATIONS IN THE TABLET CASES WERE OBJECTIVELY REASONABLE 17

A. This Court's Ruling that Defendants' Allegations Concerning the '405 and '881 Patents Raised Genuine Fact Issues Which Could Only Be Resolved After a Trial Confirms that Those Allegations Had a Reasonable Basis 17

B. Assertions of Infringement for the "Hydrophilic Polymer" Limitation Were Reasonable 20

1. Claim Construction for "Hydrophilic Polymer" 20

2. Claim Application for "20% Hydrophilic Polymer" 23

C. Defendants' Position on Other Disputed Claim Elements Was Objectively Reasonable Under *PRE* 23

1. The Limitations Requiring "Micronized Fenofibrate" ('405, '552, '670, '881 patents) and 20 to 45% by Weight "Micronized Fenofibrate" ('405, '552, and '670 patents) 24

a. Claim Construction for "Micronized Fenofibrate" 24

b. The Accused Products.....24

2. The Limitations Requiring a Dissolution Profile ('405 and '881 Patents).....25

3. The Limitations Requiring a "Hydrosoluble Carrier" ('405 Patent), an "Inert Hydrosoluble Carrier" ('552 Patent), and 20-50% By Weight "Inert Hydrosoluble Carrier" ('670 Patent) 27

4. The Limitation Requiring 0.1 to 3% By Weight of a "Surfactant" ('670 Patent) 29

5. The Limitation Requiring Covered ('670 patent).....30

D. There Was an Objectively Reasonable Basis for Disputing Teva's and Impax's Assertions of Inequitable Conduct.....30

E. There Was an Objectively Reasonable Basis for Disputing Tevas's and Impax's Assertions of Invalidity.....34

F. There Was a Reasonable Basis for Assertions of Infringement of the Curtet '726 Patent in the Tablet Cases 37

IV. THERE WAS NO *WALKER PROCESS* VIOLATION.....38

CONCLUSION.....40

TABLE OF AUTHORITIES

Page(s)

CASES

Abbott Labs. v. Impax Labs., Inc.,
2003 WL 1563426 (N.D. Ill. March 26, 2003).....6

Abbott Labs. v. Novopharm Ltd.,
2002 WL 433584 (N.D. Ill. March 20, 2002), *aff'd*, 323 F.3d 1324 (Fed. Cir. 2003) .... Passim

Abbott Labs. v. Teva Pharms. USA, Inc.,
432 F.Supp.2d 408 (D. Del. 2006).....8

AK Steel Corp. v. Sollac & Ugine,
344 F.3d 1234 (Fed. Cir. 2003).....9

Al-Site Corp. v. Opti-Ray Inc.,
28 U.S.P.Q.2d 1058 (E.D.N.Y. 1993).....12, 39

Anchor Wall Sys, Inc. v. Rockwood Retaining Walls, Inc.,
340 F.3d 1298 (Fed. Cir. 2003).....21

Anderson v. Liberty Lobby, Inc.,
477 U.S. 242 (1986)..... 8-9

Applera Corp. v. MJ Research, Inc.,
311 F. Supp.2d 263 (D. Conn. 2004).....17

Argus Chemical Corp. v. Fibre Glass-Evercoat Co., Inc.,
812 F.2d 1381 (Fed. Cir. 1987).....12, 39

Armstrong Surgical Ctr., Inc. v. Armstrong County Mem'l Hosp.,
185 F.3d 154 (3d. Cir. 1999).....10

Baltimore Scrap Corp. v. David J. Joseph Co.,
81 F. Supp. 2d 602 (D. Md. 2000).....11

Beckman Instruments, Inc. v. LKB Produkter AB,
892 F.2d 1547 (Fed. Cir. 1989).....18

Bio-Technology Gen. Corp. v. Genentech, Inc.,
267 F.3d 1325 (Fed. Cir. 2001).....19

Budde v. Harley-Davidson, Inc.,
250 F.3d 1369 (Fed. Cir. 2001).....21

C.R. Bard, Inc. v. M3 Sys. Inc.,
157 F.3d 1340 (Fed. Cir. 1998)..... Passim

Carroll Touch, Inc. v. Electro Mech. Sys.,
15 F.3d 1573 (Fed. Cir. 1993)..... Passim

Celotex Corp. v. Catrett,
477 U.S. 317 (1986).....8

Cheminor Drugs, Ltd. v. Ethyl Corp.,
168 F.3d 119 (3rd Cir. 1999) 8, 11

Comark Communs., Inc. v. Harris Corp.,
156 F.3d 1182 (Fed. Cir. 1998).....2-3, 14-15

Dippin' Dots, Inc. v. Mosey,
476 F.3d 1337 (Fed. Cir. 2007)..... 12, 38-39

Eastern R.R. Presidents Conference. v. Noerr Motor Freight, Inc.,
365 U.S. 127 (1961).....9

FilmTec Corp. v. Hydranautics,
67 F.3d 931 (Fed. Cir. 1995).....20

Gen-Probe, Inc. v. Amoco Corp.,
926 F. Supp. 948 (S.D. Cal. 1996).....19

Glaxo Group Ltd. v. Ranbaxy Pharms., Inc.,
262 F.3d 1333 (Fed. Cir.2001).....22

Harris Custom Builders v. Hoffmeyer,
834 F. Supp. 256 (N.D. Ill. 1993) 18

Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.,
343 F. Supp. 2d 272 (D. Del. 2004), *aff'd* 488 F.3d 982 (Fed. Cir. 2007) 10

In re Paulsen,
30 F.3d 1475 (Fed. Cir. 1994).....16

In re Relafen Antitrust Litig.,
346 F. Supp. 2d 349 (D. Mass. 2004) 20

In re Terazosin Hydrochloride Antitrust Litig.,
335 F. Supp. 2d 1336 (S.D. Fla. 2004) 11-12, 39

Interactive Gift Express, Inc. v. Compuserve Inc.,
256 F.3d 1323 (Fed. Cir. 2001).....21

Lupin Ltd. v. Abbott Labs.,
484 F.Supp.2d 448 (E.D. Va. 2007) 22

Miller Pipeline Corp. v. British Gas PLC,
69 F. Supp. 2d 1129 (S.D. Ind. 1999).....10

Mitek Surgical Prods., Inc. v. Arthrex, Inc.,
21 F. Supp. 2d 1309 (D. Utah 1998).....11

Nobelpharma AB v. Implant Innovations, Inc.,
141 F.3d 1059 (Fed. Cir. 1998)..... 2, 11, 38-39

Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs., Inc.,
520 F.3d 1358 (Fed. Cir. 2008).....22

Phillips v. AWH Corp.,
415 F.3d 1303 (Fed. Cir. 2005).....14

Prof'l Real Estate v. Columbia Pictures Indus., Inc.,
508 U.S. 49 (1993) ("*PRE*") ..... Passim

Q-Pharma, Inc. v. Andrew Jergens Co.,
360 F.3d 1295 (Fed. Cir. 2004)..... Passim

Scripto-Tokai Corp. v. Gillette Co.,
1994 WL 746072 (C.D. Cal. Sept. 9, 1994) 11-12

Skinder-Strauss Assocs. v. Mass. Continuing Legal Educ., Inc.,
870 F. Supp. 8 (D. Mass. 1994) 19

Sulzer Textil A.G. v. Piconol N.V.,
358 F.3d 1356 (Fed. Cir. 2004).....19

Tex. Digital Sys., Inc. v. Telegenix, Inc.,
308 F.3d 1193 (Fed. Cir. 2002).....13

Twin Cities Bakery Workers & Welfare Fund v. Astra Aktiebolag AG,
207 F. Supp. 2d 221 (S.D.N.Y. 2002)..... 19-20

United Mine Workers v. Pennington,
381 U.S. 657 (1965).....9

Walker Process Equipment, Inc. v. Food Mach. & Chem. Corp.,
382 U.S. 172 (1965)..... Passim

STATUTES

35 U.S.C. § 102 36

35 U.S.C. § 103 36

35 U.S.C. § 282 34

35 U.S.C. § 285 18

RULES

Federal Rule of Civil Procedure 12(b)(6) 8

Federal Rule of Civil Procedure 56(c) 8

INTRODUCTION

Plaintiffs seek to rewrite history. Defendants litigated two series of reasonable, closely-contested patent infringement disputes. In these litigations, each side gained some victories and sustained some losses. No one was sanctioned and no one sought to have the litigations declared "exceptional." Against this backdrop, Plaintiffs now seek to transform these cases into sham litigations and to re-litigate them under the guise of the antitrust laws. The record does not support this effort.

In this action, Defendants Abbott Laboratories ("Abbott") and Fournier Industrie et Santé and Laboratoires Fournier S.A. ("Fournier") (collectively, "Defendants") are accused of having engaged in "sham litigation" by bringing two sets of ANDA lawsuits, both involving fenofibrate products: (a) in the Northern District of Illinois alleging that capsule products described in ANDAs filed by Novopharm (Teva)[1] and Impax infringe U.S. Patent No. 4,895,726 (the "Capsule Cases"); and (b) in this Court alleging that tablet products described in ANDAs filed by Teva and Impax infringe U.S. Patent Nos. 6,074,670; 6,277,405; 6,589,552 and 6,652,881 (the "Tablet Cases"). Plaintiffs also have pled a *Walker Process* claim, accusing Defendants of asserting the '881 patent while supposedly knowing that it was unenforceable due to fraud on the PTO.

The standards for proving "sham litigation" and *Walker Process* violations are high. To prevail on a claim of sham litigation, a plaintiff must prove, by clear and convincing evidence, that the underlying litigation was both: (a) objectively baseless, and (b) filed in subjective bad faith. *Prof'l Real Estate v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 62 (1993)

[1] Novopharm, Ltd. is a subsidiary of plaintiff Teva Pharmaceutical Industries, Ltd. and was the ANDA filer in connection with Teva's fenofibrate capsule product. For the purposes of this brief, Teva and Novopharm are used synonymously in the context of the Capsule Cases.

("*PRE*"). "[S]ham litigation requires more than a failed legal theory." *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1369 (Fed. Cir. 1998). The *Walker Process* standard requires clear and convincing evidence of deceptive intent to defraud the PTO and a clear showing of reliance by the PTO. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071 (Fed. Cir. 1998). Plaintiffs cannot meet these exacting standards.

Nothing in the history of the Capsule Cases or the Tablet Cases makes them materially different from the typical patent cases that come before this Court. As in almost all patent cases, the Capsule and Tablet Cases involved legitimate disputes about claim construction. The parties presented competing constructions. Both sides' constructions had some support in the intrinsic evidence and some support in Federal Circuit case law. The courts ruled in favor of one side on some claim construction issues, and ruled in favor of the other side on the construction of other claim terms. As in many other patent cases, there were numerous summary judgment motions, some of which were granted (presenting issues for appeal) and some of which were denied (leaving disputed issues for trial). As in many other cases, once the dust settled on the summary judgment rulings, there still were genuine disputes of material fact that needed to be resolved at trial.

The Capsule Cases turned on a disputed issue of claim construction of the term "co-micronized." Although Defendants' proposed construction was not adopted, it was reasonable. Like many claim construction issues, it required the court to tread the "fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." *Comark Communs., Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998). That distinction has perplexed commentators and courts. Defendants' construction was based on the ordinary meaning and was supported by Federal Circuit precedent.

The Tablet Cases also involved reasonable disputes that are well within the norms of legitimate advocacy. The parties disagreed on the construction of eight claim terms. For six of them, this Court adopted Defendants' proposed constructions and rejected those proposed by Teva and Impax. The Court did not adopt Defendants' proposed construction only for the claim terms "hydrophilic polymer" and "covered." The construction of "hydrophilic polymer" again presented the difficult distinction "between reading a claim in light of the specification, and reading a limitation into the claim from the specification." *Id*. Defendants' proposed construction was again consistent with the ordinary meaning and had support in the specification. With respect to "covered," this Court was presented with ordinary meanings by Defendants and Teva, and decided that Teva's proposal was more appropriate in the context of the '670 patent.

Judge Jordan, who presided over the Tablet Cases, did not view Defendants' litigation positions as unreasonable or as reflective of bad faith. At the close of the Markman hearing, immediately after hearing the parties' claim construction arguments, he denied Teva's motion to end the 30 month stay on the ground that Defendants were proceeding in bad faith:

> **. . . I don't think there is a basis for saying that there has been bad faith** or undue delay in the prosecution of the litigation. . . . **That is not to say I agree with every position that each side has taken in this case. . . . [B]ut that doesn't mean that they necessarily rise to the level of bad faith . . . or something like that**. . . .(Emphasis added).

Tr. of *Markman* Hearing, 89:14-90:6 (D.I. 297 in C.A. 02-1512-SLR).

After full discovery in the Tablet Cases, Teva and Impax took a "kitchen sink" approach, inundating this Court with no fewer than nine summary judgment motions. They moved for summary judgment on almost every issue imaginable, including infringement, best mode, indefiniteness, and enablement. The Court completely denied six of their nine summary judgment motions and partially denied two others, agreeing with Defendants that there were

genuine, disputed issues of material fact that a fact finder could reasonably resolve in Defendants' favor and rejecting outright a number of the arguments made by Teva and Impax.

The summary judgment rulings in favor of Teva and Impax, on non-infringement for the '670 and '552 patents and on claim 9 of the '405 patent, were based on the construction of "hydrophilic polymer." As a result of the summary judgment rulings, two of the four Stamm patents (the '405 and '881 patents) remained for trial and two of the Stamm patents (the '670 and '552 patents) were out of the case – subject, of course, to a possible appeal on the construction of "hydrophilic polymer." Thus, the upshot of the summary judgment rulings was that a trial was needed to determine whether: (a) Teva's and Impax's products infringed either of two patents-in-suit, and (b) Teva and Impax could prove their validity and enforceability defenses by clear and convincing evidence.

Plaintiffs seek to re-argue summary judgment motions on infringement, invalidity (enablement/indefiniteness/best mode), and unenforceability (improper inventorship) that Teva and Impax lost in the Tablet Cases. They also offer invalidity and inequitable conduct theories on which Teva and Impax did not even pursue summary judgment – an implicit acknowledgement that there were triable issues of fact. Moreover, as described at pp. 30-34, 37-39, *no* evidence exists to support Plaintiffs' inequitable conduct theory (on which the sham litigation and *Walker Process* claims are premised). Plaintiffs twice deposed the alleged transgressor – a former Fournier scientist residing in France – and never once asked him about the salient facts, even in the face of his sworn declaration denying Plaintiffs' allegations.

Plaintiffs' burden is to come forward with clear and convincing evidence that no reasonable litigant could conclude, based on the existing discovery record, that Teva and Impax would fail in their invalidity (prior art) and inequitable conduct attacks. Nothing that occurred in

the Tablet Cases permits such a finding.

In essence, Plaintiffs attempt to transform ANDA patent litigation into a one-sided "winner" takes all process where the deck is stacked against a branded drug company. The goal is clear – threaten branded drug companies with significant damage exposure unless they are virtually certain they will prevail at trial and on appeal, and actually do so. But certainty is not the standard for any litigant in this country.

The question presented by this motion is, in effect, the inverse of typical summary judgment motion in a patent case. On a typical motion, the existence of a disputed issue of fact (including battles between experts) regarding infringement, validity or enforceability requires denial of the motion. In this case, a finding that there are legitimate, disputed issues regarding infringement, invalidity or enforceability compels the grant of summary judgment in favor of Defendants because such a finding necessarily means that Defendants' litigations against Teva and Impax were not "so baseless that no reasonable litigant could realistically expect to secure favorable relief" as required under PRE. 508 U.S. at 62. Here the facts show legitimate disputes in the Capsule and Tablet Cases. Under these circumstances, as a matter of law, Defendants' pursuit of the Capsule Cases and the Tablet Cases was not a "sham" and was not objectively baseless, and there was no *Walker Process* violation.

STATEMENT OF UNCONTESTED FACTS

A. The Capsule Cases

Fournier is the owner, and Abbott the exclusive licensee, of the Curtet '726 patent. *See* DJA-1490-94, '726 Patent. In 2000, Teva's Novopharm subsidiary filed an ANDA and provided Defendants with a "Paragraph IV" notice under the Hatch-Waxman Act describing Novopharm's 67 mg fenofibrate capsule. Defendants then sued Novopharm in the Northern

District of Illinois alleging infringement of the '726 patent. Novopharm later amended its ANDA to seek approval for 134 mg and 200 mg fenofibrate capsules. New Paragraph IV notices were then served and new complaints were filed alleging infringement of the '726 patent. All three cases against Novopharm were consolidated.

In 2000, Impax also filed an ANDA and provided a Paragraph IV notice describing Impax's 67 mg fenofibrate capsules to Defendants. Defendants then sued Impax in the Northern District of Illinois alleging infringement of the '726 patent. Like Novopharm, Impax twice amended its ANDA and served two additional Paragraph IV letters. Defendants, in turn, filed new complaints. All three Impax cases were consolidated.

After discovery, Novopharm moved for summary judgment of noninfringement based, *inter alia*, on its proposed construction of "co-micronized," i.e., "micronized together in the absence of other excipients." The district court adopted Novopharm's construction and relied on it in granting partial summary judgment of noninfringement to Novopharm. The grant of partial summary judgment was affirmed on appeal. *Abbott Labs. v. Novopharm Ltd.*, 2002 WL 433584 (N.D. Ill. March 20, 2002), *aff'd*, 323 F.3d 1324 (Fed. Cir. 2003).

After the district court granted summary judgment in the Novopharm case, Impax also moved for summary judgment. Shortly after the Federal Circuit's decision in the *Novopharm* case, the district court granted Impax's motion for summary judgment. *Abbott Labs. v. Impax Labs., Inc.*, 2003 WL 1563426 (N.D. Ill. March 26, 2003).

B. The Tablet Cases

Fournier is the owner, and Abbott the exclusive licensee, of the '670, '405, '552 and '881 patents (collectively, the "Stamm patents"). *See* DJA-1495-1530. All four Stamm patents have essentially the same specification.

In August 2002, Teva filed an ANDA and provided Defendants with a Paragraph IV notice describing its 54 mg and 160 mg fenofibrate tablets. Defendants then sued Teva in this Court alleging infringement of the '726, '670 and '405 patents. When the '552 and '881 patents issued later, Teva provided additional Paragraph IV notifications for them. Defendants subsequently sued Teva in this Court on the '552 and '881 patents.

In December 2002, Impax filed an ANDA and provided Defendants with a Paragraph IV notice describing its 160 mg fenofibrate tablet. Abbott and Fournier then sued Impax in this Court alleging infringement of the '670 and '405 patents. When the '552 and '881 patents issued later, Impax provided additional Paragraph IV notifications for them. Defendants subsequently sued Impax in this Court on those patents.

In the Tablet Cases, the parties disputed the construction of eight terms. For six of those terms, this Court adopted the constructions Defendants advocated. *See* D.I. 318 in C.A. 02-1512-SLR.[2] For two terms ("hydrophilic polymer" and "covered"), it adopted the construction advocated by Teva and/or Impax.

Following full discovery in the Tablet Cases, Teva and Impax filed nine contested summary judgment motions, on the issues of best mode, enablement, indefiniteness, and infringement. This Court entirely denied six of those motions and denied two others in part.[3] The Court granted partial summary judgment in favor of Teva and Impax on the issue of infringement of the '670 and '552 patents, and on claim 9 of the '405 patent. It ruled that Teva's

[2] This Court adopted four of Defendants' claim constructions word for word. This Court agreed with Defendants that two others ("granulate" and "composition") should be construed in accordance with their ordinary meanings and adopted slight variants of Defendants' proposals.

[3] *See* Sealed Memorandum Opinion (D.I. 333 in C.A. 02-1512-SLR) ("Teva SJ Op."); and Sealed Memorandum Opinion (D.I. 257 in C.A. 03-120-SLR) ("Impax SJ Op.").

and Impax's tablet products did not have a "hydrophilic polymer" under the Court's claim construction, as required by the '670 and '552 claims and by claim 9 of the '405 patent.

Following this Court's rulings on summary judgment, the case was ripe to proceed to trial on Defendants' claims of infringement of the '405 and '881 patents. Ultimately, the Tablet Cases were settled prior to trial.

THE DECISION ON DEFENDANTS' RULE 12(B)(6) MOTION

At the outset of these cases, Defendants moved under Fed. R. Civ. P. 12(b)(6) to dismiss the "sham litigation" and *Walker Process* claims for failure to state a claim on which relief can be granted. On May 26, 2006, Judge Jordan denied that motion. *See Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F.Supp.2d 408 (D. Del. 2006).

As Judge Jordan noted, Rule 12(b)(6) "requires a court to accept as true all material allegations of the complaint." *Id.* at 419. In deciding the motion to dismiss, Judge Jordan accordingly "accept[ed] [the allegations of the complaint] as true." *Id.* at 425. A different standard applies on the summary judgment motion that is now before the Court.

ARGUMENT

I. APPLICABLE LEGAL STANDARDS

A. The Summary Judgment Standard

Unlike the earlier motion under Rule 12(b)(6), a court need not and should not assume the truth of the allegations of the complaint in deciding a motion for summary judgment. Rather, summary judgment is proper where, as here, there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986); *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 121 (3rd Cir. 1999). Where, as

here, the applicable burden of proof is "clear and convincing" evidence, the non-movant must come forward with evidence sufficient to support its claims under that more demanding standard. In the absence of proof sufficient to meet this burden, summary judgment should be granted.[4]

B. The Noerr-Pennington Doctrine

Under the *Noerr-Pennington* doctrine, litigation activities generally are immune from antitrust liability, because the First Amendment protects the right to petition to influence judicial action. *Eastern R.R. Presidents Conference. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136-37 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965). Litigation activities are not immune only if the litigation is a "sham." *PRE*, 508 U.S. at 56, 60-61. To overcome *Noerr-Pennington* immunity, an antitrust plaintiff must prove by clear and convincing evidence that the underlying infringement suits were a sham or that the patents were obtained through knowing and willful fraud under *Walker Process Equipment, Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965). Under either theory, the quantum of evidence needed for this showing is very high.[5]

C. The Standards for Claims of "Sham Litigation"

In *PRE*, 508 U.S. at 60-61, the Supreme Court adopted a two-part test to determine whether a lawsuit is a sham and therefore not immune to challenge under the antitrust

---

[4] *Anderson*, 477 U.S. at 254-255 ("in ruling on a motion for summary judgment, the judge must view the evidence presented through the prism of the substantive evidentiary burden" and thus in all civil cases in which the "clear and convincing" standard applies, the "clear-and-convincing standard of proof should be taken into account in ruling on summary judgment motions "); *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1238-39 (Fed. Cir. 2003) (same).

[5] If an antitrust plaintiff is able to meet the requirements for proving sham litigation or a *Walker Process* violation, that "merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements" of its antitrust claim. *PRE*, 508 U.S. at 61. One such requirement (market definition) is the subject of a separate summary judgment motion.

laws. To prove a "sham litigation" claim under *PRE*, an antitrust plaintiff must demonstrate *both*: (a) that the underlying lawsuit was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" (*Id.* at 60); and (2) "if the petition is objectively baseless (and only if it is objectively baseless), the Court is to look to the petitioner's 'subjective motivation'." *Armstrong Surgical Ctr., Inc. v. Armstrong County Mem'l Hosp.*, 185 F.3d 154, 158 (3d. Cir. 1999). A plaintiff must meet both prongs of this test to prove sham litigation.

This motion focuses on the objective prong of the *PRE* test. To meet the objective prong of the *PRE* test, an antitrust plaintiff must show that the underlying claims were "so baseless that no reasonable litigant could realistically expect to secure favorable relief." *PRE*, 508 U.S. at 62. The critical issue is not whether the asserted claim is indeed ultimately the correct position on the issue, but whether the facts warrant "a *reasonable belief* that an allegation *may* be deemed valid." *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 343 F. Supp. 2d 272, 326 (D. Del. 2004), *aff'd* 488 F.3d 982, 1000-1001 (Fed. Cir. 2007).

Plaintiffs have the burden of proving by "clear and convincing evidence" that no reasonable litigant would have taken the positions asserted by Abbott and Fournier in the Capsule and Tablet Cases. *C.R. Bard*, 157 F.3d at 1368-69. This demanding burden makes it "very difficult" to prove objective baselessness. *Miller Pipeline Corp. v. British Gas PLC*, 69 F. Supp. 2d 1129, 1142 (S.D. Ind. 1999). Moreover, in applying the *PRE* test, courts must "resist the understandable temptation to engage in *post hoc* reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation." *PRE*, 508 U.S. at 61 n.5 (citation omitted). "Neither the bringing of an unsuccessful suit to enforce patent rights, nor the effort to enforce a patent that falls to invalidity, subjects the suitor to antitrust liability." *C.R.*

Bard, 157 F.3d at 1369.

The issue of whether the underlying litigation was objectively baseless can be resolved on summary judgment "where, as here, there is no dispute over the predicate facts underlying the legal proceeding." *PRE*, 508 U.S. at 63. A plaintiff cannot create a genuine issue of material fact by questioning the defendants' subjective belief, because the first prong of *PRE* is entirely objective. "The question is not whether [the defendant] thought the facts to constitute probable cause, but whether the court thinks they did." *Id.* at 63-64 (quotation and citation omitted).

Applying this standard, numerous courts have granted summary judgment that a suit was not objectively baseless, and appellate courts have affirmed those decisions. *See, e.g.*, *PRE*, 508 U.S. at 62-65; *Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295 (Fed. Cir. 2004); *Carroll Touch, Inc. v. Electro Mech. Sys.*, 15 F.3d 1573, 1583 (Fed. Cir. 1993); *Cheminor*, 168 F.3d at 127; *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1370 (S.D. Fla. 2004); *Baltimore Scrap Corp. v. David J. Joseph Co.*, 81 F. Supp. 2d 602, 613-21 (D. Md. 2000); *Mitek Surgical Prods., Inc. v. Arthrex, Inc.*, 21 F. Supp. 2d 1309, 1318 (D. Utah 1998); *Scripto-Tokai Corp. v. Gillette Co.*, 1994 WL 746072, at *11-14 (C.D. Cal. Sept. 9, 1994).

D. The Standards for *Walker Process* Claims

The standards for proving a *Walker Process* violation are also stringent. To come within the *Walker Process* exception to antitrust immunity, Plaintiffs must establish, again, by clear and convincing evidence, the assertion of a patent in underlying litigations that was obtained through *knowing and willful fraud*, *C.R. Bard*, 157 F.3d at 1364, and that Defendants were "aware of the fraud when bringing [the patent] suit." *Nobelpharma*, 141 F.3d at 1069.

A *Walker Process* claim requires "clear and convincing proof of intentional fraud

involving affirmative dishonesty, a deliberately planned and carefully executed scheme to defraud" the PTO. *C.R. Bard*, 157 F.3d at 1364. It is a more serious offense than inequitable conduct and is held to a higher standard requiring "(1) a false representation or deliberate omission of a fact material to patentability [to the PTO], (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted." *Id.*

A patent could be unenforceable for inequitable conduct, but the misconduct may not rise to the level of fraud required for *Walker Process*. *See Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1347 (Fed. Cir. 2007) (affirming finding of no *Walker Process* violation although patent was unenforceable for inequitable conduct). Like "sham litigation," a *Walker Process* claim is amenable to resolution on summary judgment. *See, e.g., Argus Chemical Corp. v. Fibre Glass-Evercoat Co., Inc.*, 812 F.2d 1381, 1385 (Fed. Cir. 1987); (affirming summary judgment dismissing *Walker Process* claims); *In re Terazosin*, 335 F. Supp. 2d at 1370 (granting summary judgment dismissing *Walker Process* claims); *Scripto-Tokai*, 1994 WL 746072, at *11-14 (same); *Al-Site Corp. v. Opti-Ray Inc.*, 28 U.S.P.Q.2d 1058, 1066 (E.D.N.Y. 1993) (same).

As demonstrated below, the undisputed facts and applicable law require summary judgment dismissing the "sham litigation" and *Walker Process* claims.

II. DEFENDANTS' ALLEGATIONS IN THE CAPSULE CASES WERE OBJECTIVELY REASONABLE

On the undisputed facts, Plaintiffs cannot show that the Capsule Cases were objectively baseless under *PRE*. 508 U.S. at 62-64.

The key issue in the Capsule Cases was claim construction of the term "co-micronized." Defendants' proposed construction was based on the ordinary meaning and was supported by Federal Circuit case law. Although that construction ultimately was not adopted, it

was reasonable. To this day, Teva (whose Novopharm subsidiary was a defendant in the Capsule Cases) does not claim that the Capsule Cases were shams. Impax is the only party to the Capsule Cases to make that assertion, and it did so as an afterthought, in a Second Amended Complaint filed more than a year after its other antitrust claims. *See* D.I. 355 in 03-120-SLR.

A. Defendants' Proposed Construction of "Co-Micronized" and "Co-Micronization" Was Reasonable

The Capsule Cases, like most patent cases, featured disputes on claim construction. The key dispute involved the term "co-micronized." That dispute took a typical form, with the patent owner arguing for the ordinary meaning and the accused infringer arguing for a narrower construction in light of the specification. The district court summarized the issue as follows (*Novopharm*, 2002 WL 433584 at *6):

> [Defendants in this case] argue that the term ["co-micronized"] should be given its "ordinary meaning" of "micronized with together." [Novopharm] argues that the term should be construed narrowly to mean that "fenofibrate and a solid surfactant have been micronized together in the absence of any other excipients."

Defendants' proposed construction of "co-micronized," in accordance with its undisputed ordinary meaning, was "micronized with or together." As the district court stated, "the parties do not disagree as to the common meaning of the term 'co-micronized' …. Both parties agree that the common meaning [of 'co-micronized'] is … micronized with or together." *Id*. This definition was based on the standard dictionary definition of the prefix "co-" (defined as "with or together"). *Id*.

In advocating a claim construction based on the ordinary meaning, Defendants' position was in line with then-controlling Federal Circuit precedent. *E.g.*, *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002) ("It has long been recognized in our precedent . . . that dictionaries . . . are particularly useful resources" in claim construction);

Comark, 156 F.3d at 1186-87 (the construction of "video delay circuit" should be based on its ordinary meaning "[without] recourse to the specification"). Moreover, Dr. Arthur Goldberg, an expert for Defendants, reviewed the '726 intrinsic record, and found no disclaimer or disavowal that would warrant a narrower claim scope.[6] *See* Goldberg Report, DJA-473-74, at ¶ 14.

Novopharm relied on a passage from the '726 patent specification that describes micronization of "an intimate mixture of fenofibrate and a solid surfactant" and asked the court to construe "co-micronization," narrower than its ordinary meaning, as requiring micronization of fenofibrate and a solid surfactant "*in the absence of any other excipients*." *See* DJA-1492, '726 patent, at 1:35-38; *Novopharm*, 2002 WL 433584 at *6. Thus, the claim construction issue for "co-micronized" implicated what the Federal Circuit described as "sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." *Comark*, 156 F.3d at 1186-87. Predicting which side of this "fine line" a court would come out on is fraught with uncertainty. Indeed, when the issues were being briefed in 2002-03, the law was in flux, with some Federal Circuit panels following a specification-based approach and other panels following a more dictionary-based approach. These diverging approaches were sufficiently in conflict that the Federal Circuit eventually granted *en banc* review to address the issue. *See Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

Ultimately, the district court adopted the narrower construction advocated by Novopharm, defining "co-micronized" to mean that "fenofibrate and a solid surfactant have been

[6] Dr. Goldberg explained that a person of skill in the art would not read the examples provided in the specification as limiting because they are clearly indicated as being "Preparative Examples." *See* Goldberg Report, DJA-913. In addition, Dr. Goldberg opined that a person of ordinary skill in the art would understand "intimate mixture" as used in the '726 patent simply to mean that the ingredients in the mixture are well-mixed such that they are in close proximity. *Id.* at DJA-914. Citations to "DJA" refer to pages of Defendants' Joint Appendix, filed concurrently with this motion.

micronized together ***in the absence of other excipients***." *Novopharm*, 2002 WL 433584, at *7 (emphasis added). In adopting this construction, the district court did not rely on any dictionary definition. Instead, it relied on "the examples [in the specification] …, [which mention] fenofibrate and a solid surfactant [as] the only materials micronized together." *Id.* This approach was questionable because the Federal Circuit had "cautioned against limiting the claimed invention to particular embodiments or specific examples in the specification." *Comark*, 156 F.3d at 1186 (citation omitted). Indeed, the examples cited by the district court were labeled in the specification as "Preparative Examples." *See* DJA-1492, '726 Patent, at 2:22.

On appeal in *Novopharm*, the panel affirmed the grant of summary judgment, construing "co-micronization" as "referring to co-micronization of a mixture consisting essentially of fenofibrate and a solid surfactant," *Abbott Labs. v. Novopharm Ltd.*, 323 F.3d 1324, 1330 (Fed. Cir. 2003), with the explanation that "minor impurities" were not excluded. *Id.* at 330, n.2.[7] In adopting this construction, the Federal Circuit (unlike the district court) found that the inventors had acted as "[their] own lexicographer," *id.* at 1330, citing a passage from the specification (at col. 1:35-38) that describes micronization of "an intimate mixture of fenofibrate and a solid surfactant." A reasonable litigant could question whether this passage matched the Federal Circuit's construction and also could question whether this passage rises to the level of a

[7] Impax advocated a different claim construction from the one ultimately adopted by the district court and Federal Circuit. Impax's proposed construction defined "co-micronized" to mean "the product of micronizing an intimate mixture of fenofibrate and a solid surfactant, that have not been premicronized, in the absence of other excipients. In this context, 'micronizing' means the process of reducing the particle size of a non-micronized solid particulate material in a fluid energy or jet mill to micron-sized particles (typically, to 30 microns or less); . . . it cannot mean the product of micronizing fenofibrate by itself and thereafter mixing the micronized fenofibrate with sodium lauryl sulfate and other excipients. Nor can it mean the product of micronizing fenofibrate and sodium lauryl sulfate and mixing them together with other excipients. It also cannot refer to the wet granulation and drying process." Impax Motion for Partial Summary Judgment of Non-Infringement, DJA-1121, at 11.

clear, deliberate and precise definition of the claim term. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (holding that the doctrine only applies if the intrinsic evidence defines a claim term with "reasonable clarity, deliberateness, and precision").

Defendants' construction of "co-micronized," as meaning "micronized with or together," had support in the ordinary meaning and then-controlling case law. Although not ultimately adopted, it was a reasonable construction. Under that construction, there was ample evidence that the Novopharm and Impax products met every limitation and thus infringed the '726 claims.[8] Defendants' ability to prove infringement under their construction of "co-micronized" is not seriously in dispute.

[redacted] because the '726 patent teaches that co-micronized mixtures of fenofibrate have significantly better bioavailability than mixtures of fenofibrate and a solid surfactant that are not co-micronized. *See* DJA-1492-93 at 1:35-43, 4:15-21. These facts provided more than an objectively reasonable basis to assert the '726 patent against Novopharm and Impax. *See* Goldberg Report, DJA-908-26

[8] During the capsule litigation, Defendants analyzed the Novopharm and Impax accused capsules and presented data evidencing that their formulation processes resulted in a reduction of particle size. *See* Goldberg Report, DJA-917-22, at 10-11, 15 (citing tests by Drs. Dahm, Freeman, and Nail).

B. Defendants' Construction of "Solid Surfactant" Was Reasonable

In the Capsule Cases, Defendants proposed that the term "solid surfactant" be construed to mean a surfactant that is "solid at standard temperature and pressure and in a formulated dosage form." Goldberg Report, DJA-468, at ¶ 8. Impax does not dispute that it uses SLS and that it is a solid surfactant. *See* Levy Report, DJA-823, at ¶ 33. However, Impax argues that during its wet granulation process, SLS is not solid because it is in solution. *Id.* In effect, Impax argues that the surfactant must remain solid throughout the manufacturing process. Although the Federal Circuit ultimately accepted Impax's position, Defendants' argument was objectively reasonable on the law and on the facts. On the facts: No one denies – or could deny – that the SLS in Impax's final product is a solid. *See* Goldberg Report, DJA-912-18,. Teva's expert in the underlying Capsule Cases agrees that a solution of a solid surfactant does not make it a liquid surfactant. Allen Depo., DJA-2, at 121:22-24. On the law: It was reasonable to assert that the characteristics of SLS in the final product are sufficient to prove infringement. *See Applera Corp. v. MJ Research, Inc.*, 311 F. Supp.2d 263, 272-273 (D. Conn. 2004) ("Where, as here, a claim element of a product patent does not incorporate a manufacturing process, the process of manufacture is legally irrelevant … for purpose of a literal infringement analysis.").

III. DEFENDANTS' ALLEGATIONS IN THE TABLET CASES WERE OBJECTIVELY REASONABLE

On the undisputed facts, Plaintiffs cannot show that the Tablet Cases were objectively baseless under *PRE*. 508 U.S. at 62-64.

A. This Court's Ruling that Defendants' Allegations Concerning the '405 and '881 Patents Raised Genuine Fact Issues Which Could Only Be Resolved After a Trial Confirms that Those Allegations Had a Reasonable Basis

As discussed above, the parties in the Tablet Cases disputed the construction of eight claim terms. On all but two of those disputed claim construction issues, this Court ruled in

Defendants' favor. This just underscores the absurdity of Plaintiffs' allegations. Plaintiffs would in effect have this Court conclude that the six rejected claim constructions proposed by Teva and Impax were objectively reasonable, but the two proposed by Defendants were not.

The two claim terms for which this Court rejected Defendants' proposed constructions were the terms "hydrophilic polymer" and "covered." "Hydrophilic polymer" term appears in the claims of the '670 and '552 patents, and also appears in claim 9 of the '405 patent. It does *not* appear in the other claims of the '405 patent and does not appear in the '881 patent. "Covered" appears in the '670 patent.

Following full discovery, Teva and Impax filed nine contested summary judgment motions, including motions on best mode, enablement, indefiniteness, unenforceability and infringement. Of those nine contested motions, this Court's decisions partially vindicated Defendants' position on two motions and entirely vindicated Defendants' position on six. For the '405 and '881 patents, the Court found genuinely disputed fact issues that required a trial.

This Court's findings that there were disputed issues requiring a trial on the '405 and '881 patents deserves significant weight on this motion. "An action that is well grounded enough, factually and legally, to survive a motion for summary judgment is sufficiently meritorious" to defeat an assertion that it lacked "some chance" of success on the merits and was objectively baseless. *Harris Custom Builders v. Hoffmeyer*, 834 F. Supp. 256, 261-62 (N.D. Ill. 1993) (concluding that litigation was not a sham because Harris Builders had "presented sufficient evidence to raise a genuine issue of material fact ….").

The Federal Circuit has repeatedly endorsed this principle in deciding whether a claim or defense is so baseless that its assertion makes a case "exceptional" under 35 U.S.C. § 285. *See Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir.

1989) ("we find it difficult to agree that [a] defense was 'baseless' when it survived a motion for summary judgment"); *Sulzer Textil A.G. v. Piconol N.V.*, 358 F.3d 1356, 1370 (Fed. Cir. 2004) (same); *Bio-Technology Gen. Corp. v. Genentech, Inc.*, 267 F.3d 1325, 1333 (Fed. Cir. 2001) (relying on denial of motions for summary determination in affirming district court finding that ITC litigation was not baseless). As the district court stated in *Sulzer Textil*, "it is difficult to conceive of a 'baseless' claim that survived summary judgment." *Id*.

The same principle is equally applicable in the sham litigation context. *See Gen-Probe, Inc. v. Amoco Corp.*, 926 F. Supp. 948, 958 (S.D. Cal. 1996) ("A denial of summary judgment means that the non-moving party has produced enough evidence that a rational jury could find in its favor. A party with sufficient evidence to support a jury finding has probable cause to bring a lawsuit.") (holding that the prior lawsuits did not constitute sham litigation); *Skinder-Strauss Assocs. v. Mass. Continuing Legal Educ., Inc.*, 870 F. Supp. 8, 11 (D. Mass. 1994) ("If … [plaintiff] survives a summary judgment motion … that [it] is entitled to judgment in its favor on the [sham litigation] counterclaims ….").

In *Twin Cities Bakery Workers & Welfare Fund v. Astra Aktiebolag AG*, 207 F. Supp. 2d 221 (S.D.N.Y. 2002), as here, the defendants were alleged to have engaged in "sham litigation" in an earlier ANDA case. There, as here, some (but not all) of the patents-in-suit survived summary judgment motions in the ANDA litigation and presented genuine fact disputes that could only be resolved by a fact-finder after hearing the evidence at trial. In the later antitrust case, the court dismissed the "sham litigation" claims and held (emphasis added):

> **These determinations [in the ANDA cases on summary judgment], allowing claims of infringement of four of the six asserted patents to proceed beyond summary judgment, and two of the four to proceed**

through trial, preclude any contention that defendants' litigation is so baseless as to not warrant *Noerr-Pennington* immunity.[9]

Id. at 224. The same result is appropriate here, for the same reasons.

At a minimum, this Court's finding that Defendants' claims present genuine disputed fact issues confirms what extensive evidence shows – that Defendants' assertions in the Tablet Cases had a reasonable basis under *PRE*, and thus enjoy *Noerr-Pennington* immunity.

B. Assertions of Infringement for the "Hydrophilic Polymer" Limitation Were Reasonable

1. Claim Construction for "Hydrophilic Polymer"

The claims of the '552 patent required a composition comprising at least 20% by weight "hydrophilic polymer; the claims of the '670 patent required a composition with 20-45% by weight "hydrophilic polymer."[10]

Defendants' proposed construction of "hydrophilic polymer" was "any high molecular weight compound of repeating molecular units having an affinity towards water." As Defendants' demonstrated in their *Markman* brief, that is the ordinary meaning of the term "hydrophilic polymer." *See* Abbott's and Fournier's Opening Claim Construction Brief, at 9 (D.I. 168 in C.A. 03-120-SLR).

Teva and Impax advocated a different construction, which defined "hydrophilic polymer" to mean "any high weight molecular substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein and form a gel." To support this

---

[9] *Compare FilmTec Corp. v. Hydranautics*, 67 F.3d 931, 937 (Fed. Cir. 1995) (court must make own assessment of objective merits of underlying case); *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 362-65 (D. Mass. 2004) (same).

[10] In addition, claim 9 of the '405 patent required the claimed composition to include a "hydrophilic polymer." The other asserted claims of the '405 patent did not include this limitation.

construction, Teva and Impax relied on a passage from the specification that uses the term "hydrophilic polymer" to describe "any high weight molecular substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein *and* form a gel." DJA-1508, '405 Patent, at 4:36-49 (emphasis added)). However, a proper claim construction should take into account the specification as a whole, not just an isolated excerpt. *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1379-80 (Fed. Cir. 2001) (it is "necessary to consider the specification as a whole, and to read all portions of the written description, if possible, in a manner that renders the patent internally consistent"); *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1334-35 (Fed. Cir. 2001) (considering "entirety of specification" instead of "isolated statement").

Another passage in the specification uses the term "hydrophilic polymer" in a broader sense than the passage cited by Teva and Impax, to describe a "hydrophilic polymer" as having various degrees of solubility when placed in water-based or organic solutions: "Depending on [the hydrophilic] polymer solubility, [the hydrophilic polymer] *either* dissolves **or** forms a gel **or** a solution having various degrees of thickness." DJA-1509, '405 Patent, at 6:58-63 (emphasis added). This latter description of a "hydrophilic polymer" suggests that the hydrophilic polymer does not need to *both* dissolve *and* form a gel, but could dissolve **or** form a gel **or** a solution with varying degrees of thickness. *See* Williams Report, DJA-643-45, 946-51. This kind of "varied use of a disputed term [in the specification] attests to breadth of a term rather than providing a limiting definition." *Anchor Wall Sys, Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1308 (Fed. Cir. 2003).

Moreover, the intrinsic record suggests that the narrower usage of "hydrophilic polymer" in the specification resulted from a translation error. The original French application,

which is part of the intrinsic record,[11] used the French word "ou," which means "or," in describing a "hydrophilic polymer" as a polymer that can "dissolve therein [in water] **or** form a gel." *See* D.I. 182, Ex. 5, p. 99 in C.A. 03-120-SLR. Apparently, the French "ou" was mis-translated as "and" in the U.S. application, resulting in a description of "hydrophilic polymer" as a polymer that dissolves in water **and** formed a gel.

Even setting aside the translation error, the Federal Circuit has recognized that while the term "and" is most commonly defined in its "additive sense," dictionaries "also show usage of the term to connote alternatives." *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1362 (Fed. Cir. 2008) (citing *Webster's Third New International Dictionary* (2002)) (holding that "and" was used in its alternative sense to mean "or").

In short, Defendants' proposed construction of "hydrophilic polymer" finds support in: (a) the ordinary meaning of "hydrophilic polymer"; (b) the specification's use of the term "hydrophilic polymer" in a broader sense than the one advocated by Teva and Impax; (c) evidence that the specification's narrower use of the term resulted from a translation error; and (d) dictionary definitions, which the Federal Circuit has relied upon, showing that "and" is sometimes used to mean "or." Although the district court ultimately did not adopt Defendants' construction, that construction was reasonable. Judge Jordan recognized this immediately after the *Markman* hearing, when he stated, in denying a motion by Teva to lift the 30-month stay based on allegedly improper litigation conduct, that Defendants' positions *did not* reflect any bad

[11] The French priority application was part in the '670 patent file wrapper and can be considered during claim construction. *See Glaxo Group Ltd. v. Ranbaxy Pharms., Inc.*, 262 F.3d 1333, 1337 (Fed. Cir.2001) (considering foreign priority application in claim construction analysis where it was part of the file wrapper); *Lupin Ltd. v. Abbott Labs.*, 484 F.Supp.2d 448, 452 n. 4 (E.D. Va. 2007) (foreign priority application is part of the prosecution history).

faith (D.I. 297 in C.A. 02-1512-SLR at Tr. 89:14-90:6) (emphasis added):

> **…. I don't think there is a basis for saying that there has been bad faith or undue delay in the prosecution of the litigation. …. This is not to say I agree with every position that each side has taken in this case. …. [B]ut that doesn't mean that they necessarily rise to the level of bad faith or undue delay or something like that. ….** That's now how I read the record and I've been living part of the record with you folks.

2. Claim Application for "20% Hydrophilic Polymer"

According to Teva's ANDA, its products contain [redacted] *See* DJA-409. The specification of the Stamm patents identifies PVP as an example of a hydrophilic polymer. *See* DJA-1508, '405 Patent, at 4:45-46. In addition, MCC is a "hydrophilic polymer" under Defendants' claim construction because it can form gels when mixed with water. *See* Byrn Report, DJA-493-94, 525-535, 551; Allen Depo., DJA-108, at 27:18-22; Allen Depo. DJA-11-12, at 47:24-48:2). Adding together the [redacted] Thus, Teva's ANDA provided an objectively reasonable basis for asserting that its product had 20 to 45% "hydrophilic polymer."

As for Impax, its ANDA showed that its products contain [redacted] *See* DJA-406. Thus, Impax's own ANDA provided an objectively reasonable basis for asserting that Impax's Products contained 20-45% hydropholic polymer.

C. Defendants' Position on Other Disputed Claim Elements Was Objectively Reasonable Under *PRE*

Defendants also advocated reasonable positions concerning other limitations of the Stamm patents. Claim charts and narratives comparing the Stamm patents and the accused products are included in the expert reports filed in this action. *See* Byrn Report, DJA-496-505, 554-565, 663-665, 889-897; McGinity Report, DJA-931-42.

1. The Limitations Requiring "Micronized Fenofibrate" ('405, '552, '670, '881 patents) and 20 to 45% by Weight "Micronized Fenofibrate" ('405, '552, and '670 patents)

a. Claim Construction for "Micronized Fenofibrate"

The parties agreed that micronized fenofibrate meant "fenofibrate in a particulate form, the dimensions of the particles being less than or equal to about 20 microns." *See* Joint Claim Construction Chart (D.I. 238 in C.A. 02-1512-SLR; D.I 167 in C.A. 03-120-SLR).

b. The Accused Products

Defendants' position on infringement of the "micronized fenofibrate" limitations was objectively reasonable under *PRE*. This Court's denial of Teva's and Impax's summary judgment motions on this issue, finding genuine facts disputes that could only be resolved on the evidence at trial, confirms that conclusion. Teva SJ Op. at 11-14; Impax SJ Op. at 19-24.

[redacted] It is objectively reasonable to rely on statements made in Teva's and Impax's ANDAs regarding the nature of their products as a basis for asserting infringement. *See Q-Pharma*, 360 F.3d at 1305 (affirming summary judgment of no "sham litigation" and noting that a "reasonable litigant" could rely on documents and statements from an accused infringer about an accused product instead of performing physical, pre-suit testing). In the present case, testing confirmed the presence of micronized fenofibrate in their finished products. *See* Byrn Report, DJA-489, 549-50.

Similarly, Teva's and Impax's ANDAs also provided a reasonable basis for asserting that the accused products had 20-45% fenofibrate by weight, as required by certain claims. *See Q-Pharma*, 360 F.3d at 1305. Teva's ANDA stated that its tablet products are made

with approximately [redacted] it was reasonable to assert that Teva's products contained micronized fenofibrate in the 20-45% range. *See* Byrn Report, DJA-883-87.

As for Impax, its ANDA stated that its tablet products are made with approximately [redacted] Thus, Impax's own manufacturing specifications make it reasonable to assert that some tablets with [redacted] of micronized fenofibrate would be within the claimed 45% range.

2. The Limitations Requiring a Dissolution Profile ('405 and '881 Patents)

The claims of the '405 and '881 patent are addressed to the product's "dissolution profile," *i.e.*, the rate at which fenofibrate dissolves in testing under a particular method. The claimed profile requires dissolution of at least 10% of the fenofibrate in 5 minutes, 20% in 10 minutes, 50% in 20 minutes, and 75% in 30 minutes, as measured using a particular methodology, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or with 0.025M SLS. DJA-1511, '405 Patent, at 10:28-36.

Tests conducted by Defendants' experts showed that the accused Teva and Impax products meet the claims' dissolution profile requirements. *See* Byrn Report, DJA-494-96, 659-66. These test results establish that Defendants' assertions of infringement for the dissolution

profile limitations were objectively reasonable under *PRE*.

With test results showing that the Teva and Impax products meet the claimed dissolution profile, Plaintiffs are relegated to arguing that the claims were objectively baseless because Defendants' dissolution tests were not done before the lawsuits were filed. This is not correct. Facts that become available during the course of a litigation are relevant in determining whether the suit had an objectively reasonable basis. *See PRE*, 508 U.S. at 63-64. Dissolution testing – regardless of when done – shows the properties of the Teva and Impax products. Those products bore those properties before suit was filed; the tests simply confirmed that fact.

In any event, information contained in Teva's ANDA and Impax's ANDA makes assertions of infringement of the dissolution profile limitations objectively reasonable. *See Q-Pharma*, 360 F.3d at 1305. By virtue of filing ANDAs, Teva and Impax alleged that their respective products were bioequivalent to Abbott's TriCor tablets, which unquestionably meet the claimed dissolution profile. The correlation between bioavailability and a water insoluble drug's dissolution profile is well-established. *See* Amidon Report, DJA-873, at ¶ 50. Indeed, the specification of the Stamm patents refers to this correlation between bioavailability and dissolution. *See* DJA-1507, '405 Patent, at 1:12-50. In view of these facts, an assertion that Teva's and Impax's products meet the claimed dissolution profile, as Tricor does, was objectively reasonable under *PRE*. *See* Amidon Report, DJA-872-73, at ¶¶ 48-51; Amidon Depo., DJA-124-26, at 229:15-231:21.

[redacted]

In addition, what Teva's and Impax's Paragraph IV letters left unsaid provides additional evidence of the reasonableness of assertions of infringement of the dissolution profile limitations. In their Paragraph IV letters, Teva and Impax argued at length that their respective tablet products did not infringe *other* limitations of the Stamm patents – but they did not dispute infringement of the dissolution profile limitations. Indeed, the Paragraph IV letters do not say one word about the claimed dissolution profile. *See* DJA-1239-79, 1286-1329. Teva and Impax undoubtedly would have argued noninfringement of the dissolution profile limitations if they had any basis for doing so.

Against this background, the results of dissolution testing during the litigation confirmed a conclusion that already was supported by the pre-suit evidence – that the dissolution profile of the Teva and Impax products meet the requirements of the '405 and '881 claims. Once again, assertions that Teva's and Impax's products infringed the dissolution profile limitations were objectively reasonable under *PRE*. *Carroll Touch*, 15 F.3d at 1583.

3. The Limitations Requiring a "Hydrosoluble Carrier" ('405 Patent), an "Inert Hydrosoluble Carrier" ('552 Patent), and 20-50% By Weight "Inert Hydrosoluble Carrier" ('670 Patent)

Defendants' position on infringement of the "hydrosoluble carrier" and "inert

hydrosoluble carrier" limitations were objectively reasonable under *PRE*. This Court's denial of Teva's and Impax's motions for summary judgment on this issue, finding genuine issues of disputed fact, confirms that conclusion. *See* Teva SJ Op. at 11-14; Impax SJ Op. at 24-25.

The Court adopted Defendants' proposed construction of "inert hydrosoluble carrier" as meaning "any excipient generally hydrophilic, pharmaceutically inert, crystalline or amorphous, in a particulate form, and which is soluble in an aqueous medium, notably in a gastric medium." Memorandum Opinion, at 8-12 (D.I. 318 in C.A. 02-1512-SLR). Applying this construction, assertions that the accused Teva and Impax products met the "hydrosoluble carrier" limitations had a reasonable basis under *PRE*.

In addition, the specification of the Stamm patents identifies lactose as an example of an inert hydrosoluble carrier. *See* DJA-1508, '405 Patent, at 4:31. *See* DJA-409. In short, there was ample evidence that Teva's product contained a "hydrosoluble carrier" or an "inert hydrosoluble carrier" in an amount of between 20 to 50% by weight. Certainly, that assertion was reasonable under *PRE*. *See Q*-Pharma, 360 F.3d at 1305; *Carroll Touch*, 15 F.3d at 1583.

Defendants asserted the doctrine of equivalents (DOE) for the "hydrosoluble carrier" and "inert hydrosoluble carrier" limitations, and this Court held that DOE was, in fact, available in denying Impax's motion for summary judgment on that issue. The denial of Impax's motion left for trial the question of whether the in Impax's product is a substantial equivalent for the claimed "hydrosoluble carrier" and "inert hydrosoluble carrier." As discussed above, Defendants' position on equivalents was supported by ample evidence. *See* McGinity Report, DJA-935-36, at 10. Because is exceptionally hydroswellable, it was reasonable to assert that it would be expected to perform in substantially the same way as a typical "inert hydrosoluble carrier" such as lactose in an amount of 20 to 50%. *See id.; Carroll Touch*, 15 F.3d at 1583.

4. The Limitation Requiring 0.1 to 3% By Weight of a "Surfactant" ('670 Patent)

"Surfactant" is a commonly used term of art referring to surface active agents. Surfactants are typically used as a wetting agents or emulsifiers to increase the solubility of a substance in water. *See* McGinity Report, DJA-933. *See* McGinity Report, DJA-937; DJA-406.

Assertions that Teva's and Impax's products meet this limitation had an objectively reasonable basis under *PRE*. *See Q-Pharma*, 360 F.3d at 1305; *Carroll Touch*, 15 F.3d at 1583.

5. The Limitation Requiring Covered ('670 patent)

The term "covered" was only in dispute in the Teva litigation. The term was not defined in the specification, so Defendants proposed an ordinary meaning of "appearing on or occupying some portion of the surface of," which as the Court acknowledged was a recognized definition in *Webster's Third New International Dictionary* 524 (3d ed. 1986). Memorandum Opinion, at 24-26 (D.I. 318 in C.A. 02-1512-SLR). Teva used this same dictionary for its proposed construction. Defendants' proposal was based on a standard dictionary definition and had an objectively reasonable basis.

Defendants had proof (microscopic analysis) that Teva's product contained [redacted] under either construction. *See* Byrn Report, DJA-550-51. Teva did not move for summary judgment of noninfringement of the "covered" limitation, thus effectively conceding that the issue of infringement of that limitation could only be resolved at trial based on a genuine dispute as to material facts.

D. There Was an Objectively Reasonable Basis for Disputing Teva's and Impax's Assertions of Inequitable Conduct

Like many accused infringers, Teva and Impax left no stone unturned in their search for something that could support a charge of inequitable conduct. After extensive discovery, they latched onto two documents. The first document was a memo dated May 30, 1997 from Pascale Blouquin, a scientist in Fournier's research department, which compared the suitability of two different dissolution media – SLS and a compound referred to as "tween 80" – for dissolution testing. *See* DJA-29-32. In discussing that subject, the memo included a chart that showed the results of a dissolution test – out of literally hundreds of dissolution tests

performed by Fournier scientists – on a commercial product known as Lipanthyl 200. *See* DJA-32. The second document Teva and Impax relied upon was an undated memo by Ms. Blouquin, entitled "Fenofibrate Tablets 54-160 MG Dissolution Test Conditions Development Studies," which showed dissolution data for Abbott's Tricor product. *See* DJA-33-46.

In the Tablet Cases, Teva and Impax alleged that Defendants committed inequitable conduct by: (a) supposedly concealing from the PTO the May 1997 memo and the undated memo, and (b) representing during the prosecution of the Stamm patents that the composition of Stamm's invention has a more favorable dissolution profile than products made in accordance with the prior art '726 patent. Teva and Impax allege that the May 1997 memo and the undated memo reflect dissolution profiles of products made in accordance with the '726 patent, and that the data in these memos is less favorable to patentability than dissolution data that was provided to the PTO.

For their inequitable conduct theory to make sense, Teva and Impax needed to show, by clear and convincing evidence, that someone involved in prosecution of the Stamm patents: (a) was aware of the May 1997 memo or the undated memo at some relevant time during the prosecution, and (b) withheld that information with an intent to deceive the PTO. Exhaustive discovery did not yield *any* evidence – let alone clear and convincing evidence – that *anyone* involved in prosecution of the Stamm patents was aware of either the May 1997 memo or the undated memo *at any relevant time*.

In fact, the evidence showed the opposite. The inventors (who were never employed by Fournier) were not aware of either of these internal Fournier memos. Teva and Impax did not ask the inventors of the Stamm patents about the memos during depositions. Fournier's in-house counsel and outside attorneys were not aware of them. *See* Diebolt Depo.,

DJA-7.001-.002, at 44:20 – 46:6 and 49:21 – 50:16; Grieff Depo., DJA-7.006-.008, at 137:15-25; 138:17-139:1. Abbott's attorneys were not aware of the data. *See* McNeil Depo., DJA-12.003, 97:12-20. In addition, Pascale Blouquin, the author of both memos, did not have any involvement in the prosecution of the Stamm patents. *See e.g.*, Blouquin Depo., DJA-52.002-.004, at 73:23-75:6.

In trying to link the memos to someone involved in patent prosecution, the best that Teva and Impax could do was to point out that one of the two listed recipients of the May 1997 memo was a Fournier employee named Philippe Reginault. In October 2002, during an interview, the patent examiner asked Fournier to provide a comparison between the claimed tablet and a product based on U.S. Patent No. 4,800,079 (Boyer). In the Spring of 2003 – six years after the May 1997 memo – Fournier's counsel asked Mr. Reginault for help in the '881 prosecution for the sole purpose of preparing the comparison requested by the Patent Examiner. *See* Diebolt Depo., DJA-7-7.002, at 39:23-40:3. The results of that comparative test are contained in a declaration dated June 16, 2003, included in the accompanying Appendix at DJA-1280-85.[12] *See* Diebolt Depo., DJA-7-7.002, at 39:23-40:25, 45:7-46:6, 49:21-50:16. There is no allegation that the June 2003 declaration is incorrect in any way.

In the Tablet Cases, Teva and Impax offered only speculation – but no proof – that Mr. Reginault: (a) was consistently involved in prosecution of the Stamm patents; (b) remembered the May 1997 memo and its contents six years later, in June 2003, when he prepared the declaration concerning the Boyer reference for the '881 prosecution; (c) received

[12] The only other person who was listed as a recipient of the May 1997 memo was a former Fournier employee named Maurice Tendero. There is no evidence that he was involved in any way in prosecution of the Stamm patents.

and read the undated memo (which does not list him as a named recipient), and remembered its contents in June 2003; and (d) deliberately withheld these documents with an intent to deceive the PTO. This speculation is refuted by the evidence.

Mr. Reginault stated, in a September 25, 2005 declaration under penalty of perjury, that his only involvement in prosecution of the Stamm patents was the preparation of his declaration concerning the Boyer reference in the Spring of 2003 and that when he prepared that declaration in 2003 he did not have any recollection of the May 1997 or the undated memo:

> 12. In late March 2003 … I was asked by Fournier's patent counsel to have performed a comparison of the dissolution rates of two products: [a 160 mg fenofibrate product and a product representative of the Boyer patent].
>
> 19. **Except for the '881 declaration [describing the requesting comparison to a product practicing the teachings of Boyer], I was not consulted or involved in the prosecution of [the Stamm] patent applications or any other patent applications** based on the [Stamm] technology.
>
> 21. **The 1997 Memo was written six years before** I supervised the test in connection with **the '881 Declaration**. I am listed as a recipient of the 1997 Memo and do not dispute that I may have received a copy of the memo. **I do not recall whether I reviewed this document or all of the data in it back in 1997.** The purpose of the tests reported in the 1997 Memo appears to have been to confirm the performance of the dissolution medium made of sodium lauryl sulfate ("SLS") versus a dissolution medium made of Tween 80.
>
> 22. **I certainly do not believe that in June 2003 I had a memory of the 1997 Memo or of the specific dissolution data in it** to which Teva cites because, among other things, once the Formulation Department had confirmed that 0.025 M SLS was an appropriate substitute for Tween 80, there would have been no reason to give the data any further thought. My only recollection was that it was concluded that 0.025 M SLS was an appropriate substitute.
>
> 23. **Teva also alleges that I omitted from the '881 Declaration and concealed from the USPTO, data that is contained in an undated document "**Fenofibrate Tablets 54-160 MG Dissolution Test Conditions Development Studies …."

> 24. **It is possible that I reviewed that [undated document] when I was employed by Fournier. However, when I prepared the '881 Declaration in June 2003, I did not consider or recall the data … to which Teva cites.**

See DJA-47-52 (emphasis added); *see also* Reginault Depo., DJA-15-16, at 37:11-38:2; DJA-20-21, at 185:15-186:24.

Teva and Impax deposed Mr. Reginault in the Tablet Cases, and all of the Plaintiffs deposed him again in connection with this antitrust action. In the depositions, Plaintiffs had a full opportunity to probe and challenge Mr. Reginault's sworn statements, which had been produced to Plaintiffs. Instead of questioning Mr. Reginault on these topics, Plaintiffs carefully avoided them. As a result, Mr. Reginault's sworn statements stand entirely unrebutted.

The existence of a six-year gap in time and Mr. Reginault's sworn statements that he did not recall the memos, demonstrate, beyond dispute, an objectively reasonable basis for disputing Teva's and Impax's allegations of inequitable conduct. A reasonable litigant could readily conclude that given the time period and Mr. Reginault's sworn statement, Teva and Impax would not prevail on this claim. Not surprisingly, neither Teva nor Impax saw fit to move for summary judgment on these issues during the Tablet Cases.

E. There Was an Objectively Reasonable Basis for Disputing Tevas's and Impax's Assertions of Invalidity

Under 35 U.S.C. § 282, issued patents have a statutory presumption of validity. In order to overcome that presumption Teva and Impax needed to provide clear and convincing evidence that the patents were invalid.

Defendants provided reports from two experts – Dr. Gordon Amidon of the University of Michigan, and Dr. Robert Williams of the University of Texas – demonstrating that the Stamm patents were not invalid. *See* Amidon Report, DJA-584-95, 606-16, 864-72; and

Williams Report, DJA-628-32, 647-50, 952. As explained in detail in those reports, there was more than an objectively reasonable basis for Defendants to dispute Teva's and Impax's assertions of invalidity. Indeed, the reports provide overwhelming evidence that Teva's and Impax's validity challenges were doomed to failure.

After fact and expert discovery ended, Teva and Impax moved for summary judgment of invalidity on various theories, including best mode, enablement, indefiniteness, and a supposedly false declaration on inventorship. This Court denied all of those motions, finding genuine fact disputes that could only be resolved by a fact-finder based on the evidence at trial. The Court's rulings on summary judgment confirm what the undisputed facts show – that there was an objectively reasonable basis for disputing Teva's and Impax's invalidity arguments.

Enablement: The specification provides numerous examples of how to practice the Stamm inventions, disclosing, *inter alia*, numerous excipients that can be used, numerous types of granules that practice the invention, and manufacturing descriptions. *See* Williams Report, DJA-628-32, 647-50, 952; Amidon Report, DJA-608-11. Using the teachings of the specification, one of skill in the art could readily practice the full scope of the claims without undue experimentation by generating a wide variety of formulations that meet the claims. *Id.*

Best Mode: Teva argued that the inventors had in mind, but did not disclose, a particular type of lactose for the hydrosoluble carrier. That assertion is not support by the evidence. The specification of the Stamm patent discloses the use of lactose, and the decision of what type of lactose to use would be a routine design choice for one of skill in the art. *See* Williams Report, DJA-652-56.

Indefiniteness: In asserting an indefiniteness defense, Teva relied on what this Court characterized as a "grammatically savvy" but obtuse reading (which this Court rejected) of

the claim describing the 0.025M SLS dissolution medium. *See* Memorandum Opinion, at 26-29 (D.I. 318 in C.A. 02-1512-SLR). As Defendants' expert Gordon Amidon explained, one of skill in the art would read the dissolution claim as requiring a concentration of 0.025M SLS; under that reading, the claims are not definite. *See* Amidon Depo, DJA-9, at 337:19-339:5.

False Declaration: Teva argued that Drs. Seth and Stamm did not invent the 0.025M SLS dissolution medium that is part of the some claims of the Stamm patents and, thus, improperly filed declarations stating that they were the sole inventors. As this Court recognized in denying Teva's motion for summary judgment on this issue, the dissolution medium used in testing was not the invention, but rather a measurement of the actual invention – a fenofibrate composition – which Seth and Stamm clearly invented. *See* Teva SJ Op., 8-10.

Anticipation and Obviousness: Teva and Impax did not move for summary judgment on either of these defenses, implicitly conceding, at a minimum, that there were genuine disputes as to material fact issues.

No prior art anticipates any claim of the Stamm patents or renders them obvious. *See Amidon Reports and Byrn Report.* Moreover, Plaintiffs have not identified any prior art that was not previously considered and overcome during patent prosecution. The evidence that Plaintiffs have identified that was not already considered by the PTO was the dissolution data in the May 1997 memo and the undated memo, both of which are discussed above (at pages 30-34).

Significantly, the May 1997 memo and the undated memo do not qualify as prior art under 35 U.S.C. §§ 102 or 103 because they are not printed publications and were not in use or on sale in this country *before* the January 17, 1997 priority date of the Stamm patents. By itself, this fact provides an objectively reasonable basis under PRE for disputing Plaintiffs' obviousness and anticipation arguments.

Moreover, none of the undisclosed dissolution data meets every element of any claim of the Stamm patents as an anticipatory reference must. *See* Amidon Report, DJA-864-66. The data does not render the Stamm patents obvious, because there is no obvious way that one would modify a formulation to make it dissolve faster. *See, e.g.*, Amidon Report, DJA-1330-34.

After Plaintiffs asserted their inequitable conduct theories, Fournier provided all of the undisclosed dissolution data to the PTO, along with Plaintiffs' pleadings alleging inequitable conduct, in connection with on-going patent prosecution. *See* DJA-1330-34. After receiving and considering this information, the PTO has seen fit to issue more patents in the Stamm patent family (e.g., U.S. Patent Nos. 7,037,529 and 7,041,319).

* * *

As discussed above, and in greater detail in the reports of Defendants' experts, there was ample basis under PRE for disputing Plaintiffs' invalidity theories.

F. There Was a Reasonable Basis for Assertions of Infringement of the Curtet '726 Patent in the Tablet Cases

In October 2002, when Defendants filed suit alleging infringement of the '726 patent by Teva's tablet product, the construction of the term "co-micronized" was the subject of a pending Federal Circuit appeal in the *Novopharm* Capsule Case. Until the Federal Circuit ruled in *Novopharm*, there was an objectively reasonable basis for asserting the '726 patent against Teva. *See* pages 12-17, *supra*. If the Federal Circuit had adopted Defendants' proposed construction, then Teva's tablet products clearly would have been infringing [redacted] *See* DJA-1236-37.

While the *Novopharm* appeal was pending, Defendants notified this Court and Teva that they would withdraw their claims of infringement of the '726 patent if the Federal

Circuit affirmed in the *Novopharm* case. *See* D.I. 22 at 14, in C.A. 02-1512-SLR. After the Federal Circuit ruled, Defendants did exactly that. *See* D.I. 66 in C.A. 02-1512-SLR. This conduct is indicative of good faith – not the pursuit of baseless claims.

IV. THERE WAS NO *WALKER PROCESS* VIOLATION

Plaintiffs' *Walker Process* claim fails for the same reason that their "sham litigation" claims based on inequitable conduct fails.

On the undisputed facts, Plaintiffs have no basis for claiming a *Walker Process* violation. As noted above, proof of a *Walker Process* violation requires clear and convincing evidence that: (1) the patents asserted in the underlying litigations were obtained by knowing, willful and deliberate fraud on the PTO, *C.R. Bard*, 157 F.3d at 1364, and (2) the antitrust defendants brought and maintained the underlying patent action knowing that the asserted patents were procured by fraud. *Nobelpharma,* 141 F.3d at 1069, 1071; *Dippin' Dots*, 476 F.3d at 1356. On the undisputed evidence, Plaintiffs cannot meet either prong of this test.

As demonstrated above at pages 30-34, Plaintiffs' claim rests on allegations regarding Mr. Reginault. The evidence in the Tablet Cases refuted Teva's and Impax's assertions of fraud on the PTO. That evidence included: (1) Mr. Reginault's sworn statement that his *only* involvement in the prosecution of the Stamm patents was in the Spring of 2003, when he was preparing the declaration regarding the Boyer reference for submission to the PTO; (2) Mr. Reginault's further sworn statements that when he was prepared that declaration in the Spring of 2003 he was not aware of the contents of the May 1997 memo (which he may have read six years earlier) or the undated memo (which he may never have seen); (3) undisputed evidence that Ms. Blouquin, who was the author of the two supposedly withheld documents, was not involved in prosecution of the Stamm patents; and (4) undisputed evidence that other persons

who were involved in patent prosecution (such as the inventors, Fournier personnel involved in the prosecution, and no one from Abbott) were not aware of the supposedly withheld memos. In the face of this record evidence, Defendants' assertions of fraud on the PTO rested on nothing but unsupported speculation.

The record evidence discussed above gave Defendants a more than reasonable basis for disputing Teva's and Impax's assertions of inequitable conduct. Certainly there is no clear and convincing evidence of "intentional fraud involving affirmative dishonesty, a deliberately planned and carefully executed scheme to defraud … the Patent Office" as required for a *Walker Process* violation. *C.R. Bard*, 157 F.3d at 1364; *Dippin' Dots*, 476 F.3d at 1356; *Al-Site*, 28 U.S.P.Q.2d at 1063-66.

Moreover, there is no evidence that Defendants "knowingly" brought and maintained the Tablet Cases based on patents had been procured by fraud on the PTO. There is no evidence that Defendants' knew of any wrongdoing in connection with the '881 patent or any of the Stamm patents. In fact, the record evidence refutes any assertion of fraud on the PTO. *Nobelpharma,* 141 F.3d at 1069, 1071. On the undisputed factual record, this Court should grant summary judgment dismissing the *Walker Process* claims. *See Argus Chemical*, 812 F.2d at 1385; *Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d at 1370; *Al-Site*, 28 U.S.P.Q.2d at 1063-66.

CONCLUSION

For the reasons set forth above, the Court should grant summary judgment in favor of Defendants on Plaintiffs' sham litigation and *Walker Process* claims.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

Mary B. Graham (#2256)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
mgraham@mnat.com
jparrett@mnat.com

OF COUNSEL:

William F. Cavanaugh, Jr.
Thomas W. Pippert
Chad J. Peterman
Alexis Deise
PATTERSON, BELKNAP, WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
(212) 336-2000

Attorneys for Defendant Abbott Laboratories

RICHARDS, LAYTON & FINGER, P.A.

/s/ Frederick L. Cottrell, III

Frederick L. Cottrell, III (#2555)
Anne Shea Gaza (#4093)
One Rodney Square
P.O. Box 551
Wilmington, DE 19899
(302) 651-7700
cottrell@rlf.com
gaza@rlf.com

OF COUNSEL:

William Baer
James Cooper
Anne P. Davis
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, DC 20004
(202) 942-5000

Timothy C. Bickham
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, N.W.
Washington, DC 20036-1795
(202) 429-5517

Attorneys for Fournier Industrie Et Santé and Laboratoires Fournier, S.A.

Dated: May 5, 2008
2317383

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 13, 2008, the foregoing was caused to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

In addition, the undersigned hereby certifies that true and correct copies of the foregoing were caused to be served via electronic mail on May 13, 2008 upon the following parties:

REPRESENTING DIRECT PURCHASER CLASS PLAINTIFFS (LOUISIANA WHOLESALE, ROCHESTER DRUG, MEIJER) (C.A. 05-340)	Jeffrey S. Goddess **jgoddess@rmgglaw.com** Bruce E. Gerstein **bgerstein@garwingerstein.com** Barry S. Taus **btaus@garwingerstein.com** Adam M. Steinfeld **asteinfeld@garwingerstein.com** Daniel Berger **danberger@bm.net** Eric L. Cramer **ecramer@bm.net** Peter Kohn **pkohn@bm.net** Linda P. Nussbaum **lnussbaum@kaplanfox.com** Stuart Des Roches **stuart@odrlaw.com**
REPRESENTING WALGREEN, ECKERD, KROGER, MAXI (C.A. 05-340)	Elizabeth M. McGeever **emmcgeever@prickett.com** Scott E. Perwin **sperwin@kennynachwalter.com**
REPRESENTING CVS, RITE AID (C.A. 05-340)	Elizabeth M. McGeever **emmcgeever@prickett.com** Joseph T. Lukens **jlukens@hangley.com** Steve D. Shadowen **sshadowen@hangley.com**

REPRESENTING AMERICAN SALES COMPANY INC. (C.A. 05-340)	Elizabeth M. McGeever **emmcgeever@prickett.com** Scott E. Perwin **sperwin@kennynachwalter.com**
REPRESENTING INDIRECT PURCHASER CLASS PLAINTIFFS (C.A. 05-360)	A. Zachary Naylor Pamela S. Tikellis Thomas M. Sobol Patrick E. Cafferty Jeffrey L. Kodroff Bernard J. Persky Mike Gottsch Brian Clobes Michael Tarringer Tim Fraser David Nalven Greg Matthews Christopher McDonald Kellie Safar Theodore M. Lieverman Pat Howard **tricor@chimicles.com**
REPRESENTING PACIFICARE (C.A. 05-360)	Jonathan L. Parshall **jonp@msllaw.com** William Christopher Carmody **bcarmody@susmangodfrey.com** John Turner **jturner@susmangodfrey.com** Shawn Rabin **srabin@susmangodfrey.com** Justin Nelson **jnelson@susmangodfrey.com** Ken Zylstra **zylstra@verizon.net** Mark Sandman **mms@rawlingsandassociates.com** Jeffrey Swann **js5@rawlingsandassociates.com**

REPRESENTING TEVA PHARMACEUTICALS (C.A. 02-1512)	Josy W. Ingersoll Karen E. Keller Bruce M. Gagala Christopher T. Holding Ken Cohen Elaine Blais **tricor@ycst.com**
REPRESENTING IMPAX LABORATORIES (C.A. 03-120)	Mary Matterer **mmatterer@morrisjames.com** Asim Bhansali **abhansali@kvn.com**
REPRESENTING FOURNIER (ALL CASES)	Frederick L. Cottrell, III Anne Shea Gaza Steven C. Sunshine Matthew P. Hendrickson Bradley J. Demuth Maggie DiMoscato Timothy C. Bickham **tricor@rlf.com**

/s/ James W. Parrett, Jr.

James W. Parrett, Jr. (#4292)

520842